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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,511	11/14/2003	James R. Thacker	AB-265U	9972

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EXAMINER

BERTRAM, ERIC D

ART UNIT PAPER NUMBER

3766

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/713,511	Applicant(s) THACKER ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/13/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Information Disclosure Statement

2. The information disclosure statement (IDS) submitted on 10/13/2004 was filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

3. The disclosure is objected to because of the following informalities: For whatever reason, the title of the Application appears to be missing the letter "e" in all of the words. For the sake of clarity, please correct the title by adding any missing letters.

Appropriate correction is required.

Claim Objections

4. Claim 3 is objected to because of the following informalities: the word "is" immediately following "anti-arrhythmia system" in line 4 of the claim should be --in--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 7 recites the limitation "the train of pulses" in line 2. There is insufficient antecedent basis for this limitation in the claim and the claim it depends from.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, and 4-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Mower (US 6,178,351). Mower discloses a cardiac pace and arrhythmia suppression system and method including detection circuitry for sensing atrial fibrillation in a heart by monitoring P-waves (atrial contractions) in the cardiac cycle (Col. 8, lines 20-34). Mower further describes attaching two electrodes 106 and 108 to a target atrium, with each electrode controlled by an independent stimulus generator in response to sensed atrial fibrillation (Col. 6, lines 15-30).

10. Regarding claim 2, the detection circuitry is inherently capable of detecting the termination of atrial fibrillation. Since the broadest reasonable interpretation of detect is merely to sense the existence of something, if the detection circuitry merely senses

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cardiac activity devoid of atrial fibrillation, it is detecting the termination of atrial fibrillation.

11. Regarding claims 4 and 9, the stimulus generator is configured to permit timed stimulation to the electrodes concurrently, i.e. in phase (Col. 6, lines 30-35).

12. Regarding claim 5, the electrodes are both stimulating electrodes and sensing electrodes (Col. 4, lines 26-27).

13. Regarding claims 6, 7 and 10, Mower describes supplying a train of stimulation pulses through the electrodes that are biphasic throughout (Col. 9, lines 25-30).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mower '351 in view of Mongeon et al. (US 5,620,468, hereinafter Mongeon). Mower, as described above, discloses the applicant's basic invention with the exception of deactivating stimulation when the detection circuitry detects the termination of atrial fibrillation. Attention is directed to the secondary reference of Mongeon, that discloses a method for the treatment of atrial fibrillation that continues treatment until the cessation of atrial fibrillation is detected (Col. 4, lines 54-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to stop treatment upon detection of the end of atrial fibrillation in order to prevent the delivery of unnecessary treatment to a patient.

18. Claims 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mower '351 in view of Ostroff et al. (US 6,952,610, hereinafter Ostroff) and Mongeon. Mower discloses detecting atrial fibrillation, attaching two electrodes to one atrium, delivering independently settable stimuli through the electrodes and then deactivating the stimulus (Col. 6, lines 15-30, Col 8, lines 20-35 and Col. 9, lines 45-50). Mower does not disclose, however, using a constant current stimulus, or ending stimulus after

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detecting the cessation of atrial fibrillation. Attention is directed to the first reference of Ostroff, that discloses using pulses with a constant current when treating fibrillation problems (Col. 1, lines 43-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use constant current pulses for the treatment of atrial fibrillation in order to reduce or eliminate variability due to the electrode/tissue interface.

19. Furthermore, attention is directed to the third reference of Mongeon, that discloses a method for the treatment of atrial fibrillation that continues treatment until the cessation of atrial fibrillation is detected (Col. 4, lines 54-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to stop treatment upon detection of the end of atrial fibrillation in order to prevent the delivery of unnecessary treatment to a patient.

20. Regarding claims 12-14, Mower discloses applying stimuli through the two electrodes in a timed sequence, i.e. sequential delivery (Col. 6, lines 23-32), and that the stimulus is a train of pulses that are biphasic throughout (Col. 9, lines 25-30).

21. Regarding claim 15, Mower describes using the electrodes as both stimulating electrodes and sensing electrodes (Col. 4, lines 26-27).

22. Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mower '351 in view of Ostroff et al. '610. Mower discloses a method for suppressing atrial fibrillation including attaching two electrodes to a target atrium (Col. 6, lines 15-20), detecting the onset of atrial contraction at the target atrium using a sense electrode (Col. 8, lines 20-34), and delivering independently settable stimuli through each of the

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electrodes in a timed sequence to suppress atrial fibrillation in the target atrium (Col. 6, lines 20-25). Mower does not, however, disclose that the stimuli have a constant current. Attention is directed to the secondary reference of Ostroff, that discloses using pulses with a constant current when treating fibrillation problems (Col. 1, lines 43-52). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use constant current pulses for the treatment of atrial fibrillation in order to reduce or eliminate variability due to the electrode/tissue interface.

23. Regarding claim 18, Mower describes supplying a train of stimulation pulses through the electrodes that are biphasic throughout (Col. 9, lines 25-30).

24. Regarding claim 19, Mower describes using the electrodes as both stimulating electrodes and sensing electrodes, and are used to detect the onset of atrial contraction (Col. 4, lines 26-27).

25. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mower '351. Mower discloses the applicant's basic method with the exception of stimulating the atrium so that the resulting contraction is completed faster than the atrium's native contraction. However, Mower does disclose that the speed of stimulation pulses can be increased prior to ending stimulation. Furthermore, Mower does not put an upper limit on how fast the pulses may be applied. As a result, one of ordinary skill in the art would consider it obvious to incrementally increase the speed of the pulses in order to find the timing sequence that produces the most beneficial result. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to

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increase the speed of the stimulation pulses to the point of atrial contractions occurring faster than a native contraction, since this method is suggested by Mower.

26. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mower '351 in view of Ostroff '610. Mower, as described above, discloses the applicant's basic invention with the exception of the stimulus having a constant current. Attention is directed to the secondary reference of Ostroff, that discloses using pulses with a constant current when treating fibrillation problems (Col. 1, lines 43-52).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to use constant current pulses for the treatment of atrial fibrillation in order to reduce or eliminate variability due to the electrode/tissue interface.

27. Regarding claim 22, Mower describes supplying a train of stimulation pulses through the electrodes that are biphasic throughout (Col. 9, lines 25-30).

Conclusion

28. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Alt (US 5,653,734), Mower (US 6,141,586) and Plicchi et al. (US2001/0018600) all disclose pertinent methods for the treatment of atrial fibrillation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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